K081871

SEP 2 9 2008

Attachment D – Revised Summary

510(k) Summary
for
NeuroMetrix UNIVERSAL Electrodes

1. SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451

Contact Person: Rainer Maas
Telephone: (781) 890-9989 ext. 2781

Date Prepared: August 22, 2008

2. DEVICE NAME

Proprietary Name: UNIVERSAL Electrodes
Common/Usual Name: Pre-gelled surface electrodes with leads and connector
Classification Name: 882.1320 GXY Electrode, Cutaneous

3. PREDICATE DEVICES

- Axon Systems Pre-gelled Surface Electrodes (K062198)
- NeuroMetrix Biosensors (K060584)

4. INTENDED USE

The NeuroMetrix UNIVERSAL Electrodes are intended for use with electrodiagnostic equipment for the recording of electrophysiological activity from peripheral nerves and muscles, and for peripheral nerve electrical stimulation. UNIVERSAL Electrodes are non-sterile and are for single patient use only.

5. DEVICE DESCRIPTION

Surface electrodes are the interface medium between neurodiagnostic equipment and the patient. When used for recording, they transduce bioelectric signals into electronic signals for measurement of bioelectrical phenomena in the body, such as peripheral nerve or muscle responses. When used in conjunction with stimulation circuitry in neurodiagnostic devices, they provide the interface necessary to stimulate peripheral nerves. Surface electrodes are used in the performance of nerve conduction studies (NCS). They are provided non-sterile and are designed and intended to be for single patient use only and are disposable.

- UNIVERSAL Stimulator Bar Electrode (UE-001)
- UNIVERSAL Tab Electrode Set (UE-002)
- UNIVERSAL Ring Electrode Set (UE-003)

These individually placed electrodes are not configured for specific nerves, limbs, or clinical applications. The Stimulator Bar Electrode (UE-001) is for stimulation of peripheral nerves and consists of two electrodes in a bar configuration. The Tab Electrode Set (UE-002) and the Ring Electrode Set (UE-003) each consist of three distinct electrodes that are individually placed by the user.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

A comparison of the UNIVERSAL Electrodes to the predicate Axon Systems Pre-gelled Surface Electrodes (K062198), along with testing data presented, support a finding of substantial equivalence. The UNIVERSAL Electrodes and these predicate electrodes share similar intended use, clinical applications, and technological characteristics.

The UNIVERSAL Electrodes include a connector, an electronic serial number (UE-001 only), EEPROM memory (UE-001 only), and the measurement of patient skin-surface temperature (UE-001). These technological characteristics are substantially equivalent to the NeuroMetrix Biosensors (K060584).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2008

NeuroMetrix, Inc.
c/o Mr. Rainer Maas
64 Fourth Avenue
Waltham, MA 02451

Re: K081871
Trade/Device Name: Universal Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 22, 2008
Received: September 3, 2008

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **UNIVERSAL Electrodes**

Indications for Use:

The NeuroMetrix UNIVERSAL Electrodes are intended for use with electrodiagnostic equipment for the recording of electrophysiological activity from peripheral nerves and muscles, and for peripheral nerve electrical stimulation. UNIVERSAL Electrodes are non-sterile and are for single patient use only.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081871